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An Assessment of the Effectiveness of Unannounced Safety Inspections Versus Announced Inspections in Academic Research Laboratories That Utilize Biological Hazards

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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Director of Graduate Studies (DGS), on behalf of the program; we verify that this is the final, approved version of the student's capstone including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Holley M. Trucks, Student

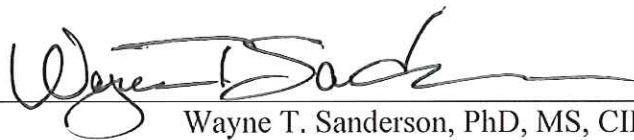
Wayne T. Sanderson, PhD, MS, CIH, Committee Chair

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An Assessment of the Effectiveness of Unannounced Safety Inspections Versus
Announced Inspections in Academic Research Laboratories That Utilize Biological
Hazards

A paper submitted in partial fulfillment of the
requirements for the degree of
Master of Public Health
in the
University of Kentucky College of Public Health
by
Holley M. Trucks

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Wayne T. Sanderson, PhD, MS, CIH, Chair



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Abstract

Inspections are integral to comprehensive biosafety programs at academic research institutions that use a wide variety of infectious agents. However, there is no standardization of biosafety inspection procedures from institution to institution. This study analyzed results of 2,098 documented inspections conducted from January 2012 through December of 2016 performed by biosafety staff at a large Research I land grant institution in order to evaluate the effectiveness of an unannounced versus the more traditional announced approach to inspection procedure. Results demonstrated that: a) more findings were noted during unannounced inspections, therefore more accurately informing biosafety staff of the true day to day conditions of the laboratory; b) the most common findings decreased over the time; and c) over time, not only did findings noted in unannounced inspections decrease, but those noted in formalized announced inspections also decreased. Therefore, the results of this study support the implementation of unannounced inspections, specifically designed to prevent interruption of laboratorians' work, as an adjunct to announced inspections at academic research institutions.

Introduction

Academic laboratories, specifically those involved in studies involving biotechnological, biomedical and agricultural research, work with a wide variety of materials, which include genetically modified organisms (GMOs) and pathogenic microbiological agents. “Despite containment measures and guidelines, laboratory infections, usually involving non-GMOs, occur more or less commonly, suggesting that biosafety rules are not always effective or followed.”¹ These laboratories rely on comprehensive biosafety programs to protect personnel, the community and environment from exposure to these materials. The laboratory inspection is an integral instrument in the toolbox of biosafety professionals. Unfortunately, methodology as well as frequency of inspection are not standardized among peer institutions. Biosafety programs at academic research institutions commonly employ the use of announced inspections and laboratory self-assessments to evaluate compliance with rules and procedures.

Studies comparing unannounced with announced inspections are extremely limited, and none are available assessing these in academic research settings. A Dutch meta-analysis and exploratory study comparing the two types of inspections in nursing homes found that if the purpose of inspection was to evaluate performance rather than the administration, that unannounced inspections were optimal; a combination of the two types of inspections offered the “best overall view.”² An unpublished study by Fiene of inspections of childcare centers and homes concluded that the addition of unannounced inspections were worthwhile to locations where there were large discrepancies in the number of findings between announced and unannounced inspections, but were not a good use of resources to

carry out for those facilities with few findings during announced inspections.³ Two additional studies evaluated the addition of announced inspections to the already existing standard of unannounced health department inspections of restaurants with the conclusion that the addition of announced inspections were effective in improving compliance with health codes.^{4,5}

To reduce the paucity of existing literature on this subject, the objective of this study was to compare inspection data gathered over a five year period from both announced and unannounced inspections at a large Research I university. The analysis of this data compared the results of unannounced and announced inspections, by use of 21 categories of findings, as well as a cumulative total score for each category. Current standards of best practices outlined in the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acids* and the CDC's *Biosafety in Microbiological and Biomedical Laboratories* are considered in formulating the recommendations of this paper.

Methods

This longitudinal study evaluated compliance in academic research laboratories utilizing biohazards at a single academic institution by analyzing results of 2,098 documented inspections--both announced and unannounced--performed by the institution's biological safety staff from January 2012, through December of 2016. The period for the study was predicated on availability of data. Prior to 2012, unannounced inspections were not routinely implemented and results from those inspections were not documented with uniformity. 2016 concludes the study with the most current data.

This study did not include inspections of clinical settings associated with human drug trials. It is common, in a university setting, that principal investigators move to other institutions or to other lab locations on the same campus, in the case of construction of new facilities, departmental re-organization, or addition of new faculty. Laboratory personnel can include principal investigators, research faculty, technical staff and graduate students, some of which transfer to other laboratories. Availability of safety staff to perform unannounced audits can also vary. For this reason, the total number of inspections performed differed from year to year. However, results from announced inspections were compared to results from unannounced inspections from the same laboratories within the same year.

Announced annual inspections were scheduled beforehand with laboratory personnel and involved a comprehensive evaluation of the facility, biohazard containment, and laboratory practices and procedures using a checklist. Announced inspections also included an interview with laboratory staff to determine understanding of the safety procedures needed for compliance with university, state, and federal regulatory policies. Results, discussed at time of inspection with laboratory staff, were then documented in the principal investigator's Institutional Biosafety Committee registration.

Unannounced "walk through" inspections, performed for the purposes of assessing day-to-day working conditions of research staff, utilized a limited checklist of solely visual metrics. By using a list of criteria that were visually assessed, biosafety staff were able to avoid disruption of ongoing research activities and minimize distractions that could present hazardous conditions for researchers. These unannounced inspections were therefore not

as comprehensive as an announced inspection, which typically took longer to perform and involved lengthy discussion with laboratory personnel. Since interaction with laboratory staff was not required for these unannounced inspections, any interaction with personnel was minimal and only involved personnel who were at that time available to discuss findings pertinent to immediate correction of safety violations. Otherwise, communication with laboratories regarding findings was via email to the principal investigator or laboratory supervisor.

Results from performed inspections were divided into two categories, announced and unannounced, per year and stratified by finding categories that were mutual to both types of inspections. To provide a means of comparison, findings prevalence (defined as number of findings over number of inspections) were calculated for each year and for each finding type. Consecutive regression analysis was performed using the total findings prevalence for announced and unannounced inspections for each year to evaluate trend. Top finding categories were also examined by linear regression. To determine whether there was significance between results of the two types of inspections, chi-square analyses were performed using the numbers of inspections with no findings versus inspections with findings. $P < 0.5$ was considered significant. Calculations were performed utilizing Microsoft Excel 2016 and R statistical software version 3.4.1. The University of Kentucky Institutional Review Board approved the study.

Results

The results of 2,098 inspections, over the course of five years, were analyzed based on 21 findings categories mutually documented in both types of inspections. Only announced inspection results from the same laboratories involved in unannounced inspections were utilized. The findings prevalence is defined as number of findings per number of inspections. The number of findings is notably larger in the unannounced inspections than in announced (Table 1). This demonstrates that since laboratorians are not prepared for the inspection, that unannounced inspections deliver a more accurate picture of normal operations within the laboratory. Linear regression for total findings prevalence is presented in Figure 1. It shows not only a significant decrease in findings prevalence over time during unannounced inspections but also that the addition of unannounced inspections has a decreasing effect on the prevalence of findings during the announced inspections. Figure 2 demonstrates the calculated standard error for these numbers.

The findings prevalence of the individual categories of findings is presented in Table 2. The category of “lab unsecured when unattended” is unique in that there is never a noted finding in the announced inspections. This demonstrates the utility of unannounced inspections, as this finding will never be caught unless there is an unannounced inspection, even if the announced inspection relies on a verbal affirmation from laboratorians on this matter. The same can be inferred for the category of “PPE worn in hallway.”

The top two categories with the highest number of findings for both announced and unannounced inspections in 2012 were “no soap and/or paper towels available for hand

washing” and the “absence of hazard labels” for equipment used in conjunction with biohazards. The third highest category of findings for announced inspections was “laboratory doors open to public corridors.” The third highest category for unannounced inspections was the absence of accurate and updated laboratory door signage indicating hazards and emergency contacts. Linear regression was performed for these categories in order to evaluate change in prevalence over the five years of collected inspections (Figures 4, 5, 6).

It should be noted that the category of “re-use or undisposed gloves” showed no demonstrable change over time for announced inspections, while the findings prevalence for this category fluctuated with no overall decrease in the unannounced inspections. The problem of disposable glove reuse is a perennial issue among laboratorians at the university and appeared unaffected by type of inspection.

Contingency tables were constructed and significance was determined for the percentages of laboratories with no findings for both types of inspections for each year. Table 3 describes the percentages of laboratories with no findings revealed by announced versus unannounced inspections. Differences were significant over a five-year period. Percentages increased each year for both types of inspections. Announced inspections in 2012 showed 75% of all labs in full compliance, allowing for a lower rate of increase than that of the unannounced inspections, which started at 16%. Unannounced inspections saw an increase of 462.5% in compliance over the course of 4 years.

Over the five year period, the starting percentage of laboratories without any findings discovered through announced inspections (75%) was approximately equal to the ending percentage of laboratories without any findings discovered with unannounced inspections (74%). Figure 7 shows the percentage of laboratories with no findings by announced and unannounced inspections by year. The linear rate of increase in percentage of laboratories with no findings over the five year period was approximately 4% announced inspections and 13% for unannounced inspections, such that over time the prevalence of laboratories with no findings discovered during announced visits approached the prevalence during unannounced visits.

Discussion

This study evaluated the differences in findings of rules or procedures infractions during unannounced inspections compared to announced inspections over a five-year period. Significantly more findings were consistently noted during unannounced inspections. Therefore, these unannounced inspections more fully captured the true day-to-day conditions of the laboratories. The most common findings decreased over the time of the study for both announced and unannounced inspections, but to a greater degree for unannounced inspections. The results of this study show that implementing unannounced inspections in laboratory assessment programs may dramatically improve safety.

Although beyond the scope of this study, the compliance observed using unannounced inspections in 2016 is nearly at the level of that seen using announced inspections in 2012.

This suggests that the original success rates of announced inspections are achievable within four years without announced inspections. Thus, arguments that unannounced inspections supporting a discounted perception of compliance rates by presenting a lower base-line are refuted by differences being recouped within a relatively short time period. This leaves little reason not to add unannounced inspections as an adjunct to any comprehensive biosafety inspection regime.

This study also exposes that some findings, such as unsecured laboratories, laboratory doors open to public corridors, and laboratory staff wearing PPE in public areas are difficult to catch without unannounced inspection. While not included in the study's inspection data, the use of biohazardous materials unregistered with the Institutional Biosafety Committee in laboratories will not likely be discovered in a timely manner by biosafety personnel without the use of unannounced inspections. These shortcomings of announced inspections add to the likelihood of loss, release, or spread of pathological microbiological materials.

Findings from formalized, scheduled, announced inspections may be ostensibly attributed to lack of preparation or lack of education as to safety policies on the part of laboratory personnel. Anticipation of being observed generally prompts laboratorians to be on their best behavior. Absent this anticipation, findings from unannounced inspections may be additionally attributed to an insufficient culture of safety in the laboratory and expose true risk of personnel health and safety.

Because this study is limited to laboratories at one academic research institution, comparative studies are needed at other institutions in order to evaluate any universal effectiveness of unannounced inspections. Furthermore, more studies are necessary to determine whether the decrease of findings over time are an effect solely of unannounced inspections or simply an effect of increased frequency of visits to the laboratories by biosafety staff.

Unannounced inspection methodology must be carefully considered before implementation as part of an inspection program. Concerns put forward in existing literature about unannounced inspections include that the surprise aspects of any visitation could promote irritation or hostility on the part of laboratorians who resent having their work interrupted. Thus, poorly orchestrated methodologies can stir up mistrust toward the biosafety staff.

A punitive approach on the part of inspectors has been shown to be counterproductive toward promotion of good rapport between laboratory staff and safety staff. Efforts to develop a robust culture of safety at the institution are inhibited by fear of safety inspectors. Indeed, studies of side effects related to unannounced inspections and their main effects on behaviors in the laboratories are needed.

This study involved a biosafety staff using an intentionally tailored inspection methodology. Solely based on a cursory battery of visual metrics, such as the discovery of disposable glove re-use and improper waste disposal containers, unannounced

inspections were designed to realistically evaluate laboratory safety issues. In this way, unannounced inspections were focused so as to prevent undue intrusion or obstruction of ongoing work in the laboratories.

While biosafety staff were available to laboratorians for consultation during these inspections, communication was unnecessary for completion of the unannounced inspection and no interaction occurred unless there was a health and safety issue that required immediate correction. Otherwise, findings were discussed with an individual not conducting bench work and/or a notice was sent afterwards to the respective principal investigator. While anecdotal, biosafety staff observed a marked increase in positive rapport with laboratorians over the five year period of this study.

Cost is a major factor in determining whether implementation of additional unannounced inspections is advisable for any given institution. Monetary evaluation of these ideas needs to take into consideration labor-hours spent by safety personnel, time spent away from research activities by laboratory personnel, and savings due to reduced injury costs. Non-monetary aspects also requiring consideration include assured safe performance of research, mutually informative and beneficial relationships between research and safety staff, employee satisfaction, and reputation among peer institutions. Future studies should evaluate the cost-benefit of adding unannounced inspections.

The practices recommended in this study may highlight other institutional needs in a more timely fashion. As an example, a rising trend in open laboratory doors to public corridors

might secondarily call attention to the need for environmental controls (ex: poor ventilation) of research facilities. Performance is enhanced by giving rise to the Hawthorne Effect, which describes a phenomenon wherein productivity increases when pertinent factors are manipulated, and most commonly refers to personnel performance enhancement by the process of being observed.⁶ Complacency, the nemesis of safety, is naturally disturbed by calling attention to the inspection process.

This paper shows that, over time, unannounced inspections facilitate greater compliance rates than announced inspections. These findings contradict at least one published opinion that announced inspections are “a more efficient use of both the inspector’s and the laboratory workers’ time.”⁷ However, this study finds that announced inspections are an accelerating adjunct to unannounced inspections. These findings are important to inspectors with limited resources, seeking maximum compliance in minimal time. Biosafety officers attempting to establish acceptable baselines need to focus on the data generated by unannounced inspections augmented by announced inspections.

Conclusion

This paper has shown that, over time, unannounced inspections facilitate greater compliance rates than announced inspections in three important ways. The utilization of unannounced, yet unobtrusive, inspections yielded more findings, demonstrated a decreasing effect on both the total number of findings and the most common findings, and positively impacted results of formalized announced inspections. It further suggests that unannounced inspections may contribute to the effective use of limited time by biosafety

staff. Further research is required to substantiate the exact relationship between unannounced inspections and these additional suggested factors.

Unannounced inspections are best used as an adjunct to announced inspections, which remain the standard method for most academic research institutions. Because institutions have limited resources, a rubric for cost-benefit analysis is suggested. Inspection data from other institutions become more informative in light of this study's analytic method. While this study stands alone in its contribution to the literature, it fits a thread of work that needs to be expanded. The results are therefore commended to the attention of future researchers.

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Table 1

Total findings for laboratories for announced and unannounced inspections 2012-2016

Finding	TOTAL #Find. ANNOUNCED 2012	total #find. unannounced 2012	TOTAL #Find. ANNOUNCED 2013	total #find. unannounced 2013	TOTAL #Find. ANNOUNCED 2014	total #find. unannounced 2014	TOTAL #Find. ANNOUNCED 2015	total #find. unannounced 2015	TOTAL #Find. ANNOUNCED 2016	total #find. unannounced 2016
Re-use or undisposed gloves	3	8	7	34	9	51	8	39	2	25
PPE worn in public corridor	0	0	0	2	0	0	0	1	0	0
No soap and/or paper towels for handwashing	6	16	4	21	7	26	9	9	1	7
Lab door open to public corridor	4	11	1	36	2	31	1	15	0	1
Evidence of food or cosmetic use in laboratory	0	5	0	10	0	18	0	10	0	1
Improper waste procedures: solid biohazardous	0	7	0	6	0	2	0	0	0	1
Improper waste procedures: sharps	1	7	1	2	2	0	1	0	0	1
Improper waste procedures: glass	0	1	0	0	0	3	0	1	0	0
Improper waste procedures: medical	0	4	5	9	0	3	3	0	0	3
Improper waste procedures: pipettes	3	9	15	30	8	19	5	3	2	2
Lab unsecured when unattended	0	13	0	23	0	33	0	15	0	3
Absence of accurate door signage	3	14	5	20	7	15	7	9	6	3
Unavailability of eye wash	1	3	3	5	6	0	3	3	0	0
Cloth chair(s) in use	3	8	11	10	4	3	4	0	0	1
Absence of filter(s) on vacuum line(s)	3	2	20	34	10	28	6	18	3	13
Absence of hazard labels	6	15	7	4	3	10	5	0	1	0
Unsecured gas cylinders	0	0	1	3	0	3	4	2	1	1
Non-research related plants or animals in lab	0	1	3	4	0	5	1	4	0	6
BSC: uncertified	1	6	1	8	0	2	0	0	0	2
BSC: obstructed air flow	2	1	5	16	4	12	3	4	4	2
BSC: absence of double trap	3	8	5	8	4	9	5	4	1	4
# Findings	39	139	94	285	66	273	65	137	21	76
# Inspections	81	81	241	241	277	277	238	238	212	212
Findings Prevalence	0.48	1.72	0.39	1.18	0.24	0.98	0.27	0.58	0.1	0.36

Figure 1

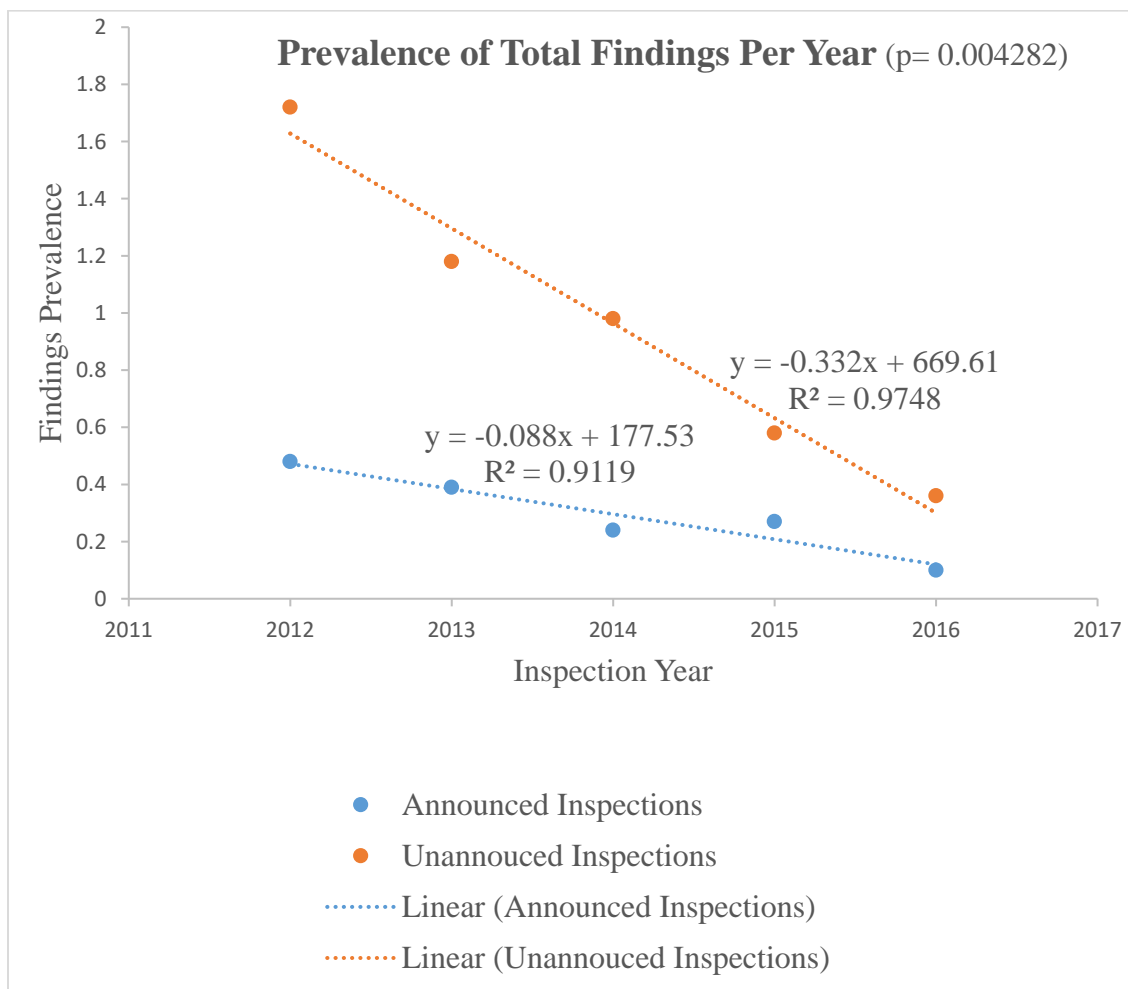


Figure 2

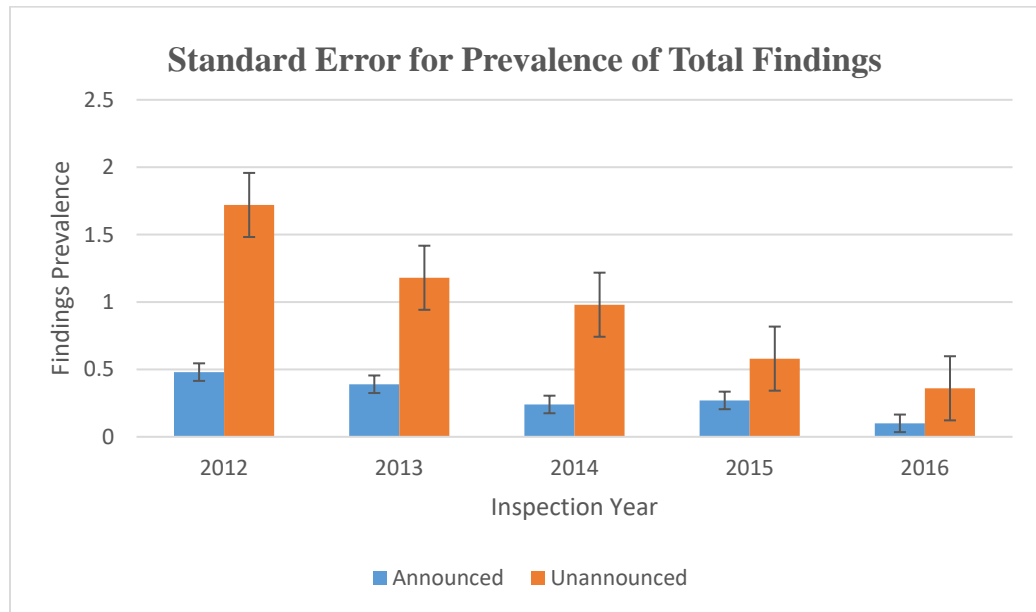


Table 2

Prevalence of individual findings for announced and unannounced inspections 2012-2016

Finding	Prevalence ANNOUNCED 2012	Prevalence unannounced 2012	Prevalence ANNOUNCED 2013	Prevalence unannounced 2013	Prevalence ANNOUNCED 2014	Prevalence unannounced 2014	Prevalence ANNOUNCED 2015	Prevalence unannounced 2015	Prevalence ANNOUNCED 2016	Prevalence unannounced 2016
Re-use of or undisposed gloves	0.04	0.10	0.03	0.14	0.03	0.18	0.03	0.16	0.01	0.12
PPE worn in public corridor	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00
No soap and/or paper towels for handwashing	0.07	0.20	0.02	0.09	0.03	0.09	0.04	0.04	0.00	0.03
Lab door open to public corridor	0.05	0.14	0.00	0.15	0.01	0.11	0.00	0.06	0.00	0.00
Evidence of food or cosmetic use in laboratory	0.00	0.06	0.00	0.04	0.00	0.06	0.00	0.04	0.00	0.00
Improper waste procedures: solid biohazardous	0.00	0.09	0.00	0.02	0.00	0.01	0.00	0.00	0.00	0.00
Improper waste procedures: sharps	0.01	0.09	0.00	0.01	0.01	0.00	0.00	0.00	0.00	0.00
Improper waste procedures: glass	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00
Improper waste procedures: medical	0.00	0.05	0.02	0.04	0.00	0.01	0.01	0.00	0.00	0.01
Improper waste procedures: pipettes	0.04	0.11	0.06	0.12	0.03	0.07	0.02	0.01	0.01	0.01
Lab unsecured when unattended	0.00	0.16	0.00	0.10	0.00	0.12	0.00	0.06	0.00	0.01
Absence of accurate door signage	0.04	0.17	0.02	0.08	0.03	0.05	0.03	0.04	0.03	0.01
Unavailability of eye wash	0.01	0.04	0.01	0.02	0.02	0.00	0.01	0.01	0.00	0.00
Cloth chair(s) in use	0.04	0.10	0.05	0.04	0.01	0.01	0.02	0.00	0.00	0.00
Absence of filter(s) on vacuum line(s)	0.04	0.02	0.08	0.14	0.04	0.10	0.03	0.08	0.01	0.06
Absence of hazard labels	0.07	0.19	0.03	0.02	0.01	0.04	0.02	0.00	0.00	0.00
Unsecured gas cylinders	0.00	0.00	0.00	0.01	0.00	0.01	0.02	0.01	0.00	0.00
Non-research related plants or animals in lab	0.00	0.01	0.01	0.02	0.00	0.02	0.00	0.02	0.00	0.03
BSC: uncertified	0.01	0.07	0.00	0.03	0.00	0.01	0.00	0.00	0.00	0.01
BSC: obstructed air flow	0.02	0.01	0.02	0.07	0.01	0.04	0.01	0.02	0.02	0.01
BSC: absence of double trap	0.04	0.10	0.02	0.03	0.01	0.03	0.02	0.02	0.00	0.02

Figure 3

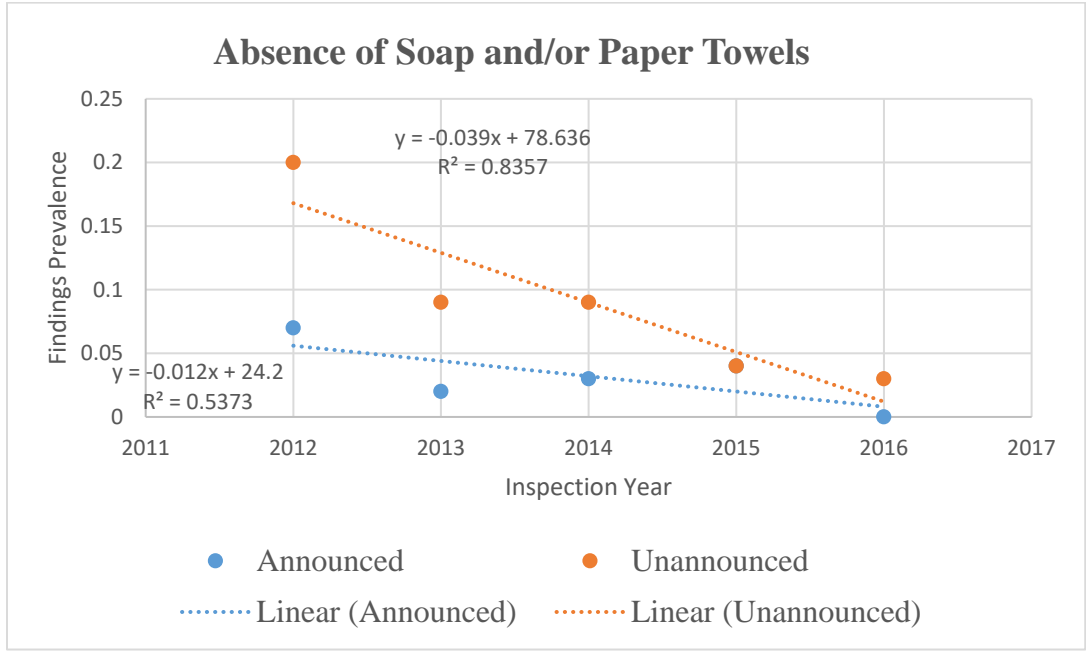


Figure 4

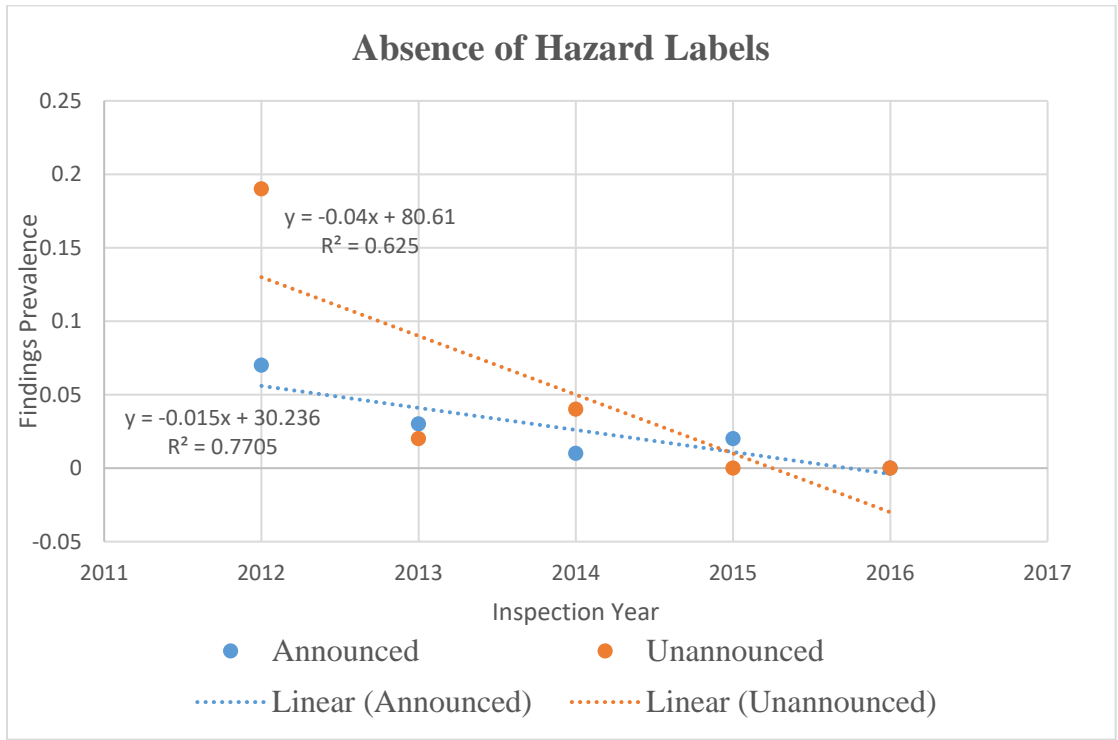


Figure 5

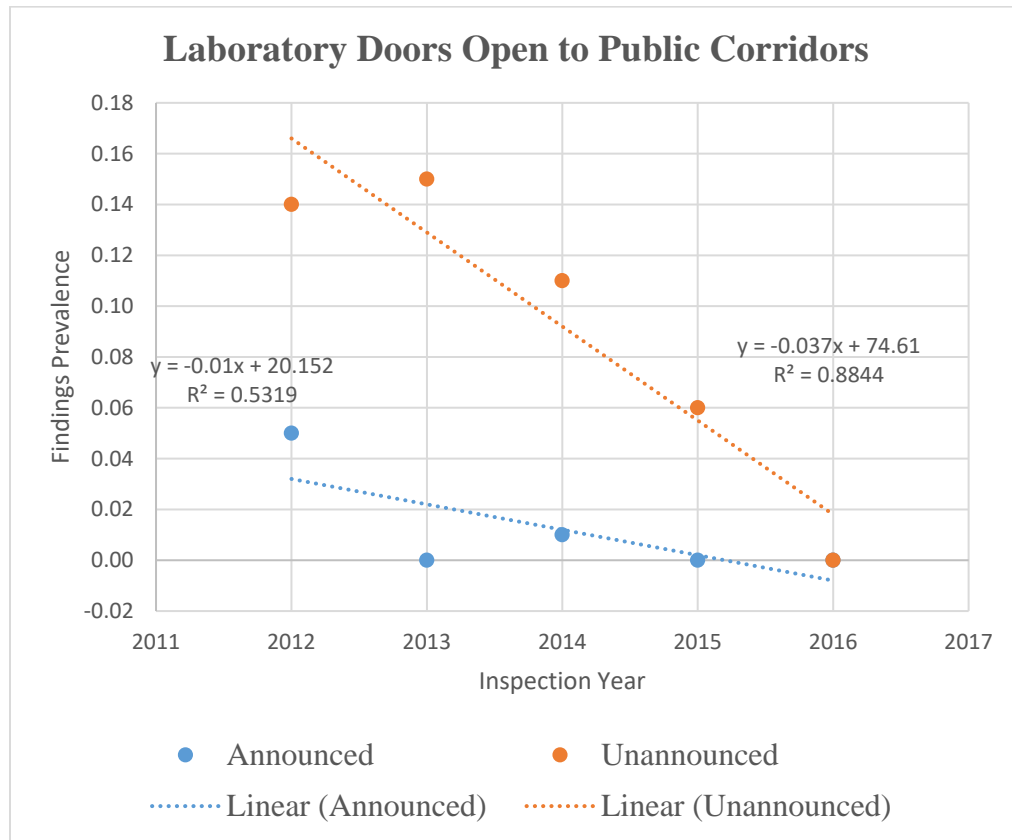


Figure 6

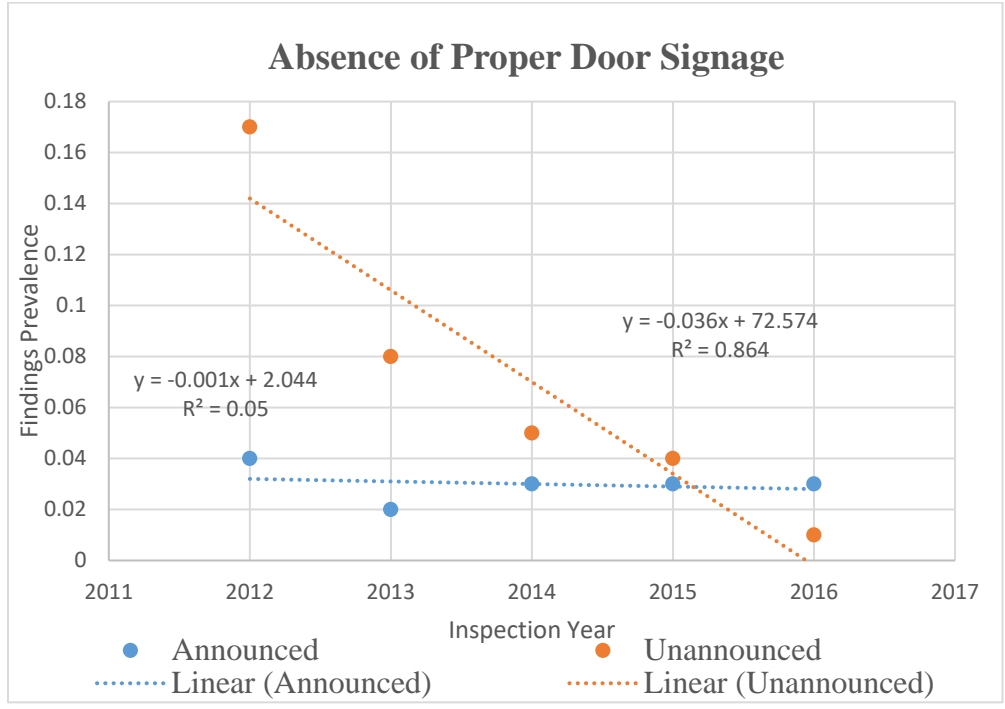
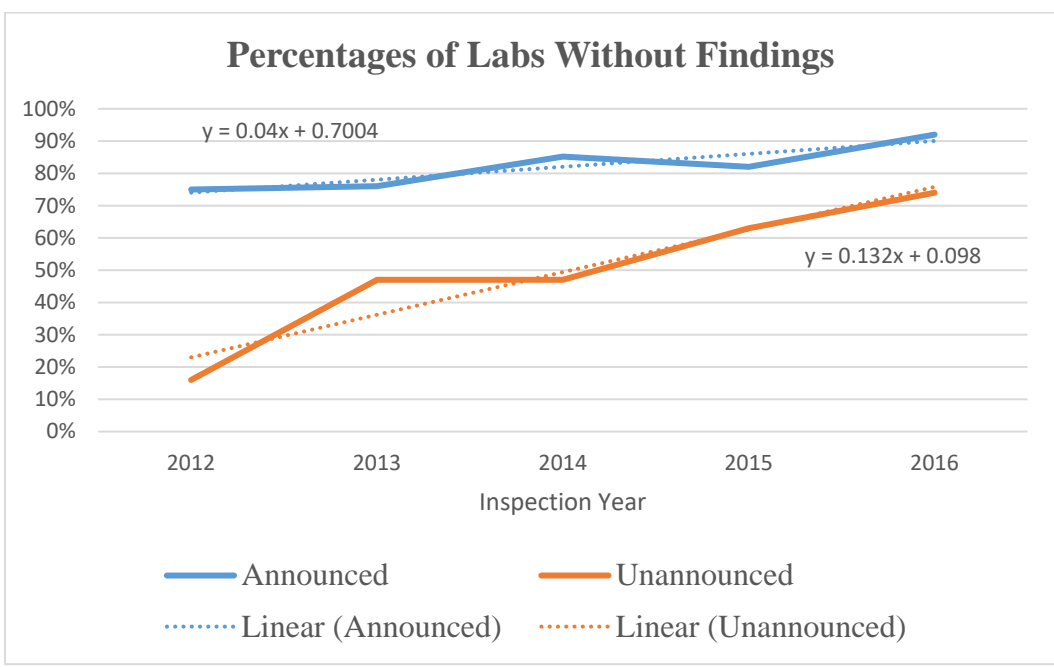


Table 3

Percentage of laboratories without any findings, determined via announced and unannounced inspection methods 2012-2106

Year	Announced	Unannounced	p value
2012	75%	16%	<.0001
2013	76%	47%	<.0001
2014	85%	47%	<.0001
2015	82%	63%	<.0001
2016	92%	74%	<.0001

Figure 7



Acknowledgments

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Initial Review

Approval Ends
August 22, 2018

IRB Number
17-0550-P2H

TO: Holley Trucks, BS, MPHc
Preventive Med & Environmental Health
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Speed Sort 0473
PI phone #: (859)257-8655

FROM: Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 17-0550-P2H

DATE: August 23, 2017

On August 23, 2017, the Medical Institutional Review Board approved your protocol entitled:

An Assessment of the Effectiveness of Unannounced Safety Inspections Versus Unannounced Inspections in Academic Research Laboratories Utilizing Biological Hazards

Approval is effective from August 23, 2017 until August 22, 2018 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. **[Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]** Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigators responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [<http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIresponsibilities>]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [<http://www.research.uky.edu/ori>]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

see blue.

Biographical Sketch

The author of this paper is Holley Maria Trucks of Lexington, Kentucky. She graduated from the Georgia State University in 1998 with a B.S. in Biology; after which she worked for the National B Virus Resource Laboratory as a research technician in viral immunology and laboratory supervisor of molecular diagnostics. Since 2008, she has been employed by the University of Kentucky as Assistant Biological Safety Officer, during which she enrolled in the Master of Public Health program at the University of Kentucky, College of Public Health. She is a member of the American Biological Safety Association, International (ABSA), Midwest Area Biosafety Network (MABioN, the Southeast Biological Association (SEBSA), and the American Association of Bioanalysts (AAB). The author's permanent address is as follows:

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